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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/024,988	02/17/1998	RANDALL W. NELSON	5015C1	9007

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EXAMINER

HOLLERAN, ANNE L

ART UNIT

PAPER NUMBER

1642

DATE MAILED: 10/22/2002

JS

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/024,988

Applicant(s)

NELSON ET AL.

Examiner

Anne Holleran

Art Unit

1642

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 March 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 31-40 and 42-47 is/are pending in the application.
- 4a) Of the above claim(s) 32,34-39 and 42-47 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 31,33 and 40 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on August 20, 2001 has been entered.

2. Claim 41 was canceled. Claims 31-40 and 42-47 are pending. Claims 32, 34-39 and 42-47, drawn to non-elected inventions, are withdrawn from consideration.

Claims 31, 33 and 40 are examined on the merits.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 31, 33 and 40 are rejected under 35 U.S.C. 102(b) as being anticipated by either Gaskell and Brownsey (Clin. Chem., 29(4): 677-680, 1983), Gaskell (Steroids, 55: 458-462, 1990), Bonfanti (Cancer Research, 50: 6870-6875, 1990) or Davoli (Anal. Chem., 65: 2679-2685, 1993).

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Claims 31, 33 and 40 are drawn to methods for quantifying an analyte in a specimen, comprising combining the specimen with an internal reference, then combining the specimen with an affinity reagent that binds both the analyte and the internal reference, and then quantifying the analyte using mass spectrometry. Claims 33 and 40 include a step that quantifying the analyte comprising comparing the ratio of the analyte spectra to the internal reference spectra to a standard curve. The internal standard is a modified analyte with shifted molecular weight and binds to the affinity reagent.

Gaskell and Brownsey teaches a method for quantifying estradiol-17 β , where a deuterated estradiol internal standard is added to a plasma sample, which is then mixed with solid-phase coupled antiserum specific for both the labeled and unlabeled estradiol. The extract is dried and analyzed by GC-MS. For quantitation, the ratios of the estradiol to deuterated estradiol were compared to a standard curve (page 678, first through second columns).

Gaskell teaches a method for quantifying DHA-S, where a deuterated DHA-S internal standard is added to a serum sample, which is then added to an immunoaffinity column. The immunoaffinity eluate was analyzed by gas-chromatography-mass spectrometry. For quantification, the ratios of the DHA-S and deuterated internal standard are compared to a standard curve (page 460, first through second columns).

Bonfanti teaches a method for quantifying O⁶-butylguanine, where a deuterated internal standard is added to a serum sample, which is then loaded onto an immunoaffinity column. The immunoaffinity column eluate is analyzed by gas chromatography-mass spectrometry. For quantification, the ratios of the O⁶-butylguanine and deuterated internal standard were compared to a standard curve (page 6871, second column).

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Davoli teaches a method for quantifying diethylstilbestrol, where deuterated internal standards are added to urine samples, which are then loaded onto immunoaffinity columns. The eluate was then analyzed by fast atom bombardment mass spectrometry. Quantification was made by comparison to a standard curve (page 2680, bottom of 2nd column – page 2681, and page 2685, first column).

Thus, either of Gaskell and Brownsey, Gaskell, Bonfanti or Davoli teaches the methods as claimed.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the Office should be directed to Anne Holleran, Ph.D. whose telephone number is (703) 308-8892. Examiner Holleran can normally be reached Monday through Friday, 9:30 am to 2:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa, Ph.D. can be reached at (703) 308-3995.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist at telephone number (703) 308-0196.

Anne L. Holleran
Patent Examiner
October 18, 2002


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